

REMARKSStatus of the claims:

With the above amendments, claims 18, 20, 21, 22, and 25-28 have been amended. Claims 31-33 have been added. Claims 18-33 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Most of the amendments are simply amendments of form. Other support for the amendments to claims 18, 22, 26, 27, and 28 comes from page 4, lines 13-14. Reconsideration is respectfully requested in light of the following remarks.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 18-30 have been rejected under 35 USC §112, first paragraph for insufficient written description. The Examiner asserts that there is insufficient support for a genus because only one species is disclosed (i.e., for maize). The Examiner further asserts that SEQ ID NO. 3 does not meet the element of a gene of 4.4 kbp (i.e., the Examiner says that 4.359 kbp is not 4.4 kbp). Applicants traverse and disagree that there is only one species, when one takes into account the number of significant figures. The claimed 4.4 kbp has two significant figures. When 4.359 kbp is rounded to two figures, it rounds to 4.4 kbp. Accordingly, there are two species to support the genus. Further, the claims have been amended to recite "about a

4.4 kbp gene" which has support at page 4, lines 13-14 in the written description. With this amendment, there can be little doubt that the claims now encompass both species.

Applicants assert that they had full possession of the scope of the claims at the time of filing the application. By claiming about a 4.4 kbp gene, a finite number of polynucleotide sequences fit within the scope of independent claim 18. This finite number of polynucleotide sequences mean that every conceivable nucleotide structure can be immediately envisaged. Further, Applicants have provided a screening method in Example 3 that allows one to test for aldehyde oxidase activity (see page 17, line 16 et seq.). Thus, any potential nucleotide sequence that falls within the scope of, for example, claim 18 can be readily assayed. Accordingly, one of skill in the art would readily recognize that the Applicants had full scope of the claimed invention at the time of filing the application.

The Examiner further asserts that the primers enumerated in claim 18 are not a structural property of the nucleotide genus and that any of a number of polynucleotides can be amplified under different PCR conditions using these primers. Applicants submit that the Examiner is discussing possibilities that are outside the scope of the claims. For example, claim 18 claims "an isolated polynucleotide encoding an aldehyde oxidase enzyme". The assay discussed in Example 3 would allow one of

skill in the art to easily screen any of the nucleotide sequences to look for activity. Accordingly, Applicants assert that Applicants had full possession of the claimed invention at the time of filing the application. In other words, the Examiner's argument that these amplified polynucleotides may code for other enzymes is irrelevant. Enzymes which do not possess the requisite enzymatic activity (i.e., being an aldehyde oxidase enzyme) are outside the scope of claim 18. The rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

Claims 18-30 have also been rejected under 35 USC §112, first paragraph for an alleged lack of enablement.

Applicants submit that the Examiner has failed to meet the burden of presenting a *prima facie* case as to why the claims would not be enabled. See *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993). *Wright*, citing *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971) states

*When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.*

The Examiner has failed to meet this initial burden. Even if the Examiner had met this burden, Applicants have provided two examples that work. Absent some evidence from the Examiner that any members of the claimed genus would not work, one must assume that the full scope of the claimed invention is enabled by the specification. Consequently, claims 18-30 are enabled for the full scope of the invention.

Moreover, the Examiner cites *In re Wands* for enumerating the factors that are to be considered when determining enablement. The Examiner cites the screening of aldehyde oxidase enzymes as one of the factors that would require undue experimentation. Applicants submit that the Court of Appeals for the Federal Circuit in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) stated

*Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'.*

Applicants submit that the amount of experimentation needed to practice the full-scope of the claimed invention is not 'undue'. In particular, one of the factors that the examiner says would require "undue experimentation" has expressly been rejected by the Court of Appeals for the Federal Circuit. Applicants submit that the present claims should be considered enabled by the present specification.

Applicants submit that one of skill in the art would know how to make and use the invention without undue experimentation. All of the factors that the Examiner asserts would have to be optimized at the top of page 6 of the Office Action (e.g. annealing temperatures, Mg and template concentrations, sequencing of putative clones and screening of aldehyde oxidase enzymes) fall within the scope of routine experimentation. Applicants have provided an assay that allows one of skill in the art to readily determine what polynucleotide sequences will encode aldehyde oxidase enzymes that are active (see Example 3 on page 17, line 16 et seq.). Thus, the full scope of the claimed invention can be practiced without undue experimentation. The rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 18, 20-22, and 25-28 have been rejected under 35 USC §112, second paragraph for being indefinite.

The Examiner has recommended changing part (e) of claims 18, 20-22, and 26-28 as follows: ". . .a nucleotide sequence encoding an amino acid sequence of a 4.4 Kbp gene obtainable from a plant, [which] wherein said 4.4 Kbp gene is amplifiable. . .". Applicants have incorporated the Examiner's suggestion with slight modification and amended the claims to recite "wherein said gene

of about 4.4 Kbp is amplifiable". Applicants believe that this non-narrowing claim amendment obviates the rejection. Withdrawal of the rejection is respectfully requested.

The Examiner asserts that claims 18, 22, 26 and 27 should be amended as follows: ". . . and [having a nucleotide] wherein said polynucleotide has a sequence selected from the group consisting of . . .". The claims have been amended accordingly. With this non-narrowing amendment, it is believed that the rejection has been obviated. Withdrawal of the rejection is respectfully requested.

The Examiner asserts that "The isolated polynucleotide . . . derived from maize plant" is indefinite. Applicants have amended claims 20 and 21 so that the word "derived" has been changed to "isolated". It is believed that with this amendment, the rejection has been obviated. Withdrawal of the rejection is respectfully requested.

The Examiner asserts that claim 21 should be amended to recite "(Zea mays L)" instead of "(Zea mays". Applicants believe that in the Response filed September 14, 2001, that the last line of claim 21 was missing. Thus, it is believed with the presentation of the above-amended claim 21 that this rejection has been obviated. Withdrawal of the rejection is respectfully requested.

Regarding the rejection over claim 25, Applicants have added the word "cell" after the word "plant" so that claim 25 recites ". . . wherein the host cell is a plant cell". It is believed that with this amendment, that claim 25 can no longer be considered vague or indefinite. Withdrawal of the rejection is respectfully requested.

The Examiner recommended some amendments to claim 26. Applicants have amended claim 26 to incorporate the ideas of the Examiner, however, it is believed that the current non-narrowing amendment has clearer language. Withdrawal of the rejection is respectfully requested.

Claim 28 has also been amended to address the Examiner's rejections. The non-narrowing claim amendment incorporates the Examiner's suggestions. Withdrawal of the rejection over claim 28 is respectfully requested.

Further, regarding claim 28, line 1, the Examiner asserts that it is unknown what is meant by the term "controlling production". Applicants submit that "controlling production" refers to both time and amount. With an inducible promoter, one can control the time at which the promoter starts to produce (or overproduce) the protein (for example, by adding IPTG). Depending on the strength of the promoter used, protein may be made in large amounts or in lesser amounts. Thus, by controlling production Applicants are able to determine the time the promoter functions

as well as the amount of protein produced. With the above description, Applicants believe that the phrase "controlling production" is neither vague nor indefinite. Withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that a passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$920.00 is attached hereto.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.



If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

Claim 18. (Twice Amended) An isolated polynucleotide encoding an aldehyde oxidase enzyme, wherein said enzyme oxidizes an aldehyde compound to a carboxylic acid, and [having a nucleotide] wherein said polynucleotide has a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 2;

(b) a nucleotide sequence shown by SEQ ID NO: 1;

(c) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 4;

(d) a nucleotide sequence shown by SEQ ID NO: 3; and

(e) a nucleotide sequence encoding an amino acid sequence of about a 4.4 Kbp gene obtainable from a plant, [which] wherein said gene of about 4.4 Kbp is amplifiable with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 13 and a PCR primer selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 15.

Claim 20. (Twice Amended) The isolated polynucleotide according to claim 18, which is [derived] isolated from maize plant (*Zea mays* L).

Claim 21. (Three times Amended) The isolated polynucleotide according to claim 19, which is [derived] isolated from maize plant (*Zea mays* L).

Claim 22. (Twice Amended) A plasmid comprising a polynucleotide encoding an aldehyde oxidase enzyme, wherein said enzyme oxidizes an aldehyde compound to a carboxylic acid, and [having a nucleotide] wherein said polynucleotide has a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 2;

(b) a nucleotide sequence shown by SEQ ID NO: 1;

(c) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 4;

(d) a nucleotide sequence shown by SEQ ID NO: 3; and

(e) a nucleotide sequence encoding an amino acid sequence of about a 4.4 Kbp gene obtainable from a plant, [which] wherein said gene of about 4.4 Kbp is amplifiable with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 13 and a PCR primer selected from the

group consisting of SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 15.

Claim 25. (Amended) The transformed host cell according to claim 23, wherein the host cell is a plant cell.

Claim 26. (Twice Amended) A process [for] of constructing an expression plasmid which comprises ligating in a functional manner

(1) a promoter capable of functioning in a plant cell upstream from,

(2) a polynucleotide encoding an aldehyde oxidase enzyme, wherein said enzyme oxidizes an aldehyde compound to a carboxylic acid, and [having a nucleotide] wherein said polynucleotide has a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 2;

(b) a nucleotide sequence shown by SEQ ID NO: 1;

(c) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 4;

(d) a nucleotide sequence shown by SEQ ID NO: 3; and

(e) a nucleotide sequence encoding an amino acid sequence of about a 4.4 Kbp gene obtainable from a

plant, [which] wherein said gene of about 4.4 Kbp is amplifiable with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 13 and a PCR primer selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 15, and

(3) a terminator [capable of functioning] functional in a plant [in a functional manner and in the order described above] downstream from the polynucleotide (2).

Claim 27. (Twice Amended) An expression plasmid comprising:

(1) a promoter capable of functioning in a plant cell,  
(2) a polynucleotide encoding an aldehyde oxidase enzyme, wherein said enzyme oxidizes an aldehyde compound to a carboxylic acid, and [having a nucleotide] wherein said polynucleotide has a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 2;

(b) a nucleotide sequence shown by SEQ ID NO: 1;

(c) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 4;

(d) a nucleotide sequence shown by SEQ ID NO: 3; and

(e) a nucleotide sequence encoding an amino acid sequence of about a 4.4 Kbp gene obtainable from a plant, [which] wherein said gene of about 4.4 Kbp is amplifiable with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 13 and a PCR primer selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 15, and

(3) a terminator capable of functioning in a plant which are ligated in a functional manner and in the order described above.

Claim 28. (Twice Amended) A process for controlling production of an aldehyde oxidase in a transformed host cell which comprises

introducing[,] into a host cell[,] an expression plasmid comprising:

(1) a promoter [capable of functioning] functional in a plant cell upstream from,

(2) a polynucleotide encoding an aldehyde oxidase enzyme, wherein said enzyme oxidizes an aldehyde compound to a carboxylic acid, and having a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 2;

- (c) a nucleotide sequence encoding an amino acid sequence shown by SEQ ID NO: 4;
- (d) a nucleotide sequence shown by SEQ ID NO: 3;
- and
- (e) a nucleotide sequence encoding an amino acid sequence of about a 4.4 Kbp gene obtainable from a plant, [which] wherein said gene of about 4.4 Kbp is amplifiable with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 8, and SEQ ID NO: 13 and a PCR primer selected from the group consisting of SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 15, and
- (3) a terminator [capable of functioning] functional in a plant and downstream from the polynucleotide (2), which are ligated in a functional manner [and in the order described above] to transform said host cell whereby the production of aldehyde oxidase of the transformed host is controlled.

Claims 31-33 have been added.